CHARGE: 402(a)(3)—contained insects while held for sale.

DISPOSITION: 9–21–59. Consent—claimed by Velvet Peanut Products Div. of Sunshine Biscuit, Inc., Detroit, Mich. The article was sorted, cleaned, and converted into peanut butter.

26595. Shelled peanuts. (F.D.C. No. 43340. S. Nos. 62–708 P, 62–710 P, 79–895/7 P.)

QUANTITY: 1,989 125-lb. bags at Detroit, Mich.

SHIPPED: Between 5–29–59 and 6–24–59, from McRae and Cordele, Ga., and Norfolk, Va.

LIBELED: 8–17–59, E. Dist. Mich.

CHARGE: 402(a)(3)—contained insects while held for sale.

DISPOSITION: 9–21–59. Consent—claimed by Velvet Peanut Products Div. of Sunshine Biscuits, Inc., Detroit, Mich. The article was sorted, cleaned, and converted into peanut butter.

26596. Shelled peanuts and cocoa beans. (F.D.C. No. 44212. S. Nos. 77–014/5 P.)

QUANTITY: 50 119-lb. bags of peanuts and 750 132-lb. bags of cocoa beans, at Seattle, Wash., in possession of Washington Chocolate Co.

SHIPPED: 8–14–59 and 10–26–59, from Ilheus, Brazil, and Houston, Tex.

LIBELED: 1–29–60, W. Dist. Wash.

CHARGE: 402(a)(4)—the articles had been held under insanitary conditions whereby they may have become contaminated with filth.

DISPOSITION: 2–4–60. Consent—claimed by Washington Chocolate Co. Segregated; 214 lbs. of peanuts and 1,590 lbs. of cocoa beans destroyed, and 14,193 lbs. of cocoa beans converted for use in making fertilizer.

VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE

26597. Mineral water. (F.D.C. No. 35395. S. Nos. 62–733 L, 62–735 L.)

QUANTITY: 353 cases, 6 ½-gal. btls. each, and 81 5-gal. carboys, at Memphis, Tenn., in possession of Mountain Valley Distributors (Mountain Valley Water Co.).

SHIPPED: 6–5–53 and 7–24–53, from Hot Springs, Ark., by Mountain Valley Spring Co.

LABEL IN PART: (Btl.) "Mountain Valley Mineral Water * * * A naturally pure mildly-alkaline mineral water. * * * it is ideal for regular use by children and adults * * * Visitors in Hot Springs, Ark., usually drink at least 8 glasses each 24 hours * * * Bottled by Mountain Valley Spring Co., Hot Springs, Arkansas."

ACCOMPANYING LABELING: Pamphlets entitled, "Your Health Begins With Nature," "The Importance of Mountain Valley Water in Arthritic and Rheumatic Disorders," "The Importance of Mountain Valley Water in Kidney and Bladder Disorders," "Mountain Valley Water from Hot Springs, Arkansas, in Pregnancy and Care of Children," "The Story of Mountain Valley Mineral Water from Hot Springs, Arkansas," "Is Your Trouble Mineral Deficiency?," "Facts

About Mountain Valley Mineral Water from Hot Springs, Arkansas," "Why Everyone Should drink Two Quarts of Water Each Day," "Helping to Stay Young Through Minerals," and "How Much Mountain Valley Mineral Water Should I Drink?"

LIBELED: 8–19–53, W. Dist. Tenn.

CHARGE: 403(a)—when shipped and while held for sale, the accompanying labeling of the article contained false and misleading representations that cooking steams away some of the mineral-laden moisture in food; that common foods cannot be relied upon as an adequate source of essential minerals; the lack of necessary minerals is one of the missing links in the health measures taken by the average person; minerals help to offset the damaging effects of toxins and wastes; drinking Mountain Valley Water regularly helps the body control the amount of nutrition taken in and the amount of waste eliminated; the influence of Mountain Valley Water on the metabolic process, the changing of food to heat energy, is most healthful and increases the assimilation of foods; the magnesium bicarbonate, 52.66 parts per million, in Mountain Valley Water helps to neutralize excessive uric acid thereby assisting the elimination of toxins which the body must throw off; the silica, 15.57 parts per million, in Mountain Valley Water which carries the minerals to points of assimilation is itself passed off by the body through pores, the glands and elimination organs; aluminum sulphate, 7.59 parts per million, in Mountain Valley Water, is a purification agent, among other things, and serves as a mild diuretic eliminant; potassium is a good oxidizing agent and helps regulate the availability of nourishment taken in and the amount of waste thrown out; the minerals in Mountain Valley Water help the kidneys manufacture urea and uric acid; minerals increase resistance to infection; it has been determined with alarm that some foods which are normally considered excellent sources of certain minerals, no longer contain them because the soil where they were grown has lost a portion of these elements; calcium deficiency is usually accompanied with the inability of the body to utilize vitamin B_1; cobalt stimulates the body's blood-making system and is used in synthesizing vitamin B_{12} in the body; the trace of cobalt in Mountain Valley Water may be of inestimable value in nutrition, especially for people residing in areas fed from cobalt-deficient soil; a shortage of zinc disturbs genital functions, nitrogen assimilation and normal hair growth; and falling out of hair and hair changes seem to be directly connected with the presence or absence of zinc, and as it is possible that zinc deficiency is quite frequent, the drinking of Mountain Valley Water on a regular basis should help to supply the needs of this element; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its mineral content and its label failed to reveal the fact, as required by the regulations, that the need for sulfur and cobalt, manganese, fluorine, zinc and bromine, in human nutrition had not been established; and its label failed also to state, as required by the regulations, the proportion of the minimum daily requirement for children and adults for calcium, phosphorus, iron, and iodine supplied by the article when consumed in a specified quantity during a period of one day, and the quantity of manganese, zinc, bromine, sulfur, cobalt, potassium magnesium, copper, and fluorine in a specified quantity.

The libel alleged also that the article was misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6023.

DISPOSITION: On 9–8–53, Mountain Valley Sales Co. filed a claim for the water, and a motion for removal and transfer to the United States District Court for the Eastern District of Arkansas.

On 10–19–53, an order was entered that the case be transferred to such court. On 11–2–53, the United States Attorney for the E. Dist. Ark. and the attorney for the claimant filed a stipulation to transfer the case to the W. Dist. Ark., and on the same day the case was transferred to that district. On 11–23–53, the Judge of the District Court of the W. Dist. Ark. on his own motion, ordered the case remanded to the E. Dist. Ark. The memorandum opinion on which the order was based is set forth as follows:

MILLER, *District Judge:* "The record in this case reflects the existence of a serious jurisdictional question and it is the duty of the court on its own motion to determine that question.

"In Moore's *Federal Practice*, Second Edition, page 2330, in discussing Rule 12(h) of the Federal Rules of Civil Procedure, the learned author said:

> A party may always suggest that the court lacks jurisdiction of the subject matter, or the court may raise such defect on its own initiative.

"In *Hackner, et al.* v. *Guaranty Trust Company of New York, et al.*, 2nd Circuit, 117 F. 2d 95, the court at page 97 of the opinion said:

> Appellant's objections to the timeliness or form of the motion to dismiss are unavailing, as jurisdictional issues may be raised by the court at any time on its own motion.

"In *Clark, Director*, v. *Paul Gray, Inc., et al.*, 306 U.S. 583, 83 L. Ed. 1001, 59 S. Ct. 744, the court at page 588 of 306 U.S. said:

> A motion of appellants in the court below to dismiss the bill of complaint for want of the jurisdictional amount was withdrawn, and the jurisdiction of the district court is not challenged here. But on the argument, it appearing doubtful whether the 'matter in controversy' exceeded 'the sum or value of' $3,000.00, § 24(1) of the Judicial Code; 28 U.S.C. § 41(1), we raised the question whether the jurisdictional amount was involved, as was our duty.

"In *Louisville & Nashville Railroad Company* v. *Mottley*, 211 U.S. 149, 53 L. Ed. 126, 29 S. Ct. 42, the court at page 152 of 211 U.S. said:

> We do not deem it necessary, however, to consider either of these questions, because, in our opinion, the court below was without jurisdiction of the cause. Neither party has questioned that jurisdiction, but it is the duty of this court to see to it that the jurisdiction of the Circuit Court, is not exceeded. This duty we have frequently performed of our own motion.

"In the instant case no one has questioned the jurisdiction of this court but, as above stated, it is the duty of the court to examine and determine the question for itself. Jurisdiction cannot be conferred by agreement but only by statute.

"The suit was filed in the United States District Court for the Western District of Tennessee on August 19, 1953, for seizure and condemnation of certain articles under and in accordance with the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. 301, et seq.). The articles sought to be seized and condemned were situated in the City of Memphis, within the territorial jurisdiction of the Federal Court for the Western District of Tennessee. The libelant, inter alia, prayed that all persons having any interest therein be cited to appear herein and answer the aforesaid premises; that this court decree the condemnation of the aforesaid article and grant libelant the costs of this proceeding against the claimant of the aforesaid article; that the aforesaid article be disposed of as this court may direct pursuant to the provisions of said Act; and that libelant have such other and further relief as the case may require.

"After due and timely notice of the filing of the libel, the Mountain Valley Sales Company, a corporation organized and existing under the laws of the State of Arkansas and having its principal office in the City of Hot Springs, County of Garland, State of Arkansas, filed its claim in which it alleged that it

> is the true and bona fide owner of and herein makes claim for the aforesaid 353 cases, more or less, each containing 6½ gallon bottles, and the 81–5 gallon carboys, more or less, of an article labeled in part 'Mountain Valley Mineral Water,' which are the subject matter of the libel filed herein on August 19, 1953.

"On the same date, the claimant filed its motion for removal and transfer and renewed its allegation that it is an Arkansas corporation, with its principal place of business in the City of Hot Springs in Garland County, Arkansas, 'which is in the Western District of Arkansas.'

"The motion was based upon Section 304(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. 334(a). The prayer of the motion is that the court immediately remove and transfer this case either to the Eastern District of Arkansas or to some other district which is within reasonable proximity of claimant's principal place of business and is contiguous to the district in which said place of business is located.

"The motion was heard on October 16 and the court, in granting the motion, said:

> The law provides that the court shall, by order, unless good cause to the contrary shown, specify a district of reasonable proximity to the claimant's principal place of business, to which district the case shall be removed for trial. The formal order of removal recites that the court does hereby find that the claimant is an Arkansas corporation having its principal place of business in Hot Springs, Arkansas, which is located within the Western Judicial District of Arkansas, and that a judicial district of reasonable proximity to the claimant's principal place of business is the Eastern Judicial District of Arkansas, Western Division, at Little Rock, Arkansas; and the court further finds that the motion of claimant is well taken and should be granted, no good cause to the contrary having been shown, under the direction and authority of Section 304(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. 334(a).

"In accordance with the order, the papers and record were transmitted to the United States District Court for the Eastern District of Arkansas, Western Division, at Little Rock, Arkansas, and were filed in that court on October 20, 1953. On November 2, 1953, Honorable James T. Gooch, United States Attorney for the Eastern District of Arkansas, as attorney for libelant, and Messrs. Wright, Harrison, Lindsey & Upton, attorneys for claimant, filed a stipulation in which they stipulated, 'that the cause may be transferred forthwith to the United States District Court, Western District of Arkansas, Hot Springs Division.' On the same date, the court entered an order transferring the case in accordance with the stipulation, and the papers and records were filed herein on November 10, 1953.

"As heretofore stated, the libel was filed under 21 U.S.C.A., § 334, which provides:

> (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale * * * after shipment in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found.

"The record does not clearly disclose upon what authority the case was transferred to this court. It is clear that 28 U.S.C.A., § 1404 does not apply since the original action could not have been brought in this District because the articles sought to be condemned were not then and are not now within the territorial jurisdiction of this court. *Fettig Canning Company* v. *Steckler*, 7th Circuit, 188 F. 2d 715; *United States* v. *Reid*, D.C.E.D. Ark., 104 F. Supp.

260; *United States* v. *23 Gross Jars, more or less, of Enca Cream, et al.*, N.D. Okla., 86 F. Supp. 824.

"21 U.S.C.A., § 334(a), does not authorize or permit the removal of a case of this nature to the district within which claimant's principal place of business is located. In *United States* v. *23 Gross Jars, etc., supra*, the court said:

> Since Section 1404(a) does not apply, the special venue section of 21 U.S.C.A. does. This section allows removal in this type action to district courts 'of reasonable proximity to the claimant's principal place of business.' The phrase has been interpreted to exclude the district or division in which claimant's principal place of business is found.

"See *United States* v. *91 Packages, more or less, Nutrilite Food Supplement, etc.*, D.C.N.J., 93 F. 763; *United States* v. *600 Units containing Nue-Ovo, etc.*, D.C., W.D., Mo., 60 F. Supp. 144; *United States* v. *26 Dozen Bottles etc., of Wheatemin Brand Cevigards*, D.C., Mich., 60 F. Supp. 626.

"The United States District Court for the Western District of Tennessee could not have transferred the case to this court because the claimant's principal place of business is situated in the Western District of Arkansas, Hot Springs Division, and it seems perfectly clear that the transfer to the Eastern District of Arkansas was entirely proper and in accordance with the statute. When the case was transferred to the Eastern District of Arkansas, it was to a district required by the statute under which the Tennessee Federal Court acted, and, even though the libelant and the claimant stipulated that the court in the Eastern District of Arkansas should transfer the case to this court, such stipulation or agreement and the order of the court of the Eastern District of Arkansas cannot give this court jurisdiction. In *United States* v. *Six Dozen Bottles, more or less of Dr. Peter's Kuriko*, E.D. Wisc., 55 F. Supp. 458, Judge Duffy said:

> The power of removal is exclusively conferred under the act upon the court of original jurisdiction, barring of course the existence of a stipulation of the parties on the subject. As the latter element does not obtain in the instant situation, this court has no power to grant the requested removal. In other words, the right to removal is completely exhausted and no longer exists in this proceeding.
>
> Claimant contends, however, that this court may order the requested removal under Sec. 334(f)(2) of the act, which provides: 'The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.'
>
> As pointed out, the proceeding was removed, pursuant to the statute, to this court 'for trial' and not for any other purpose. The language of the act last quoted is consistent with such limitation and expressly negatives any power in this court to grant further removal on application. A claimant in proceedings of this nature is limited to a single application for removal which must be made to the court of original jurisdiction. My conclusions have complete support in the legislative history of the controlling statutory provisions.

"The order of transfer of the court of the Eastern District of Arkansas is not the law of the case and it is the duty of this court to remand the case to that court. *United States* v. *Reid, supra*, page 266, 104 F. Supp.; *United States* v. *23 Gross Jars, more or less, of Enca Cream, et al., supra*, at page 826 of 86 F. Supp.; *United States* v. *26 Dozen Bottles, etc., Wheatemin Brand Cevigards, supra*.

"Therefore, an order should be entered remanding the case to the United States District Court for the Eastern District of Arkansas, Western Division."

Thereafter, on 12–2–53, claimant filed a motion in the W. Dist. Ark., to set aside the order of Judge Miller made on 11–23–53. The motion was overruled by Judge Miller on 12–11–53 (117 F. Supp. 110).

On 12–21–53, the claimant filed in the U.S. District Court for the E. Dist. Ark., a motion to dismiss or re-transfer the case. The motion was based on grounds that the court of the E. Dist. Ark. was without jurisdiction because the action was properly transferred from the E. Dist. Ark. to the W. Dist. Ark. by a valid order entered on 11–2–53, after a stipulation between the parties was made under the authority of Section 304(a) of the Federal Food, Drug, and Cosmetic Act. The motion alleged that the order of the U.S. District Court for the W. Dist. Ark. entered on 11–23–53, remanding the cause to the U.S. District Court for the E. Dist. Ark., was void. On 1–11–54, the Government filed its objection to the motion to dismiss or re-transfer for reason that the jurisdiction to try the case was vested exclusively in the U.S. District Court for the E. Dist. Ark.

On 6–16–55, Judge Trimble, Chief Judge of the U.S. District Court for the E. Dist. Ark., ruled in an opinion (135 F. Supp. 333), that his prior order (on 11–2–53) transferring the case pursuant to the stipulation, was proper and that the court of the E. Dist. Ark. was without jurisdiction to proceed.

Thereafter, the Government filed with the United States Court of Appeals for the Eighth Circuit, a petition for writ of mandamus to compel the District Judge of the E. Dist. Ark. to vacate his order of 6–14–55, and retain jurisdiction of the action. The petition for writ of mandamus was denied by the United States Court of Appeals for the Eighth Circuit in the following opinion which was handed down on 10–19–55 (226 F. 2d 238):

VOGEL, *Circuit Judge:* "By order of this court dated August 15, 1955, the petitioner, United States of America, was granted leave to file its petition for a writ of mandamus wherein petitioner asked that the respondents herein show cause before this court why a writ of mandamus should not issue requiring the United States District Court for the Eastern District of Arkansas and the Honorable Thomas C. Trimble, Chief Judge of said court, to vacate its order of June 14, 1955, denying jurisdiction in the case of *United States of America, Libelant,* v. *353 cases,* more or less, each containing 6 one-half gallon bottles, etc., Libelee, and Mountain Valley Sales Company, a corporation, Claimant, Civil No. 2682, and retain jurisdiction of such action and dispose of the case in accordance with proper legal procedure.

"The facts out of which the matter arose are as follows:

> On August 19, 1953, the United States filed libel of information in the Western District of Tennessee against certain merchandise, praying seizure in condemnation in accordance with the Federal Food, Drug and Cosmetic Act (21–U.S.C. 301, et seq.), alleging that the merchandise was misbranded. No stipulation for removal of the case to another district was entered into and upon petition for removal and transfer, the District Court for the Western District of Tennessee transferred the case to the District Court for the Eastern District of Arkansas.

"On November 2, 1953, the United States Attorney for the Eastern District of Arkansas, representing the libelant, and the attorney representing the claimant signed and filed a stipulation providing that the case should be transferred from the Eastern District of Arkansas to the Hot Springs Division of the Western District of Arkansas, the principal place of claimant's business. Chief Judge Trimble, respondent, signed an order so transferring the case.

"On November 23, 1953, Judge John E. Miller, of the Hot Springs Division of the Western District of Arkansas, on his own motion, ordered that the case be remanded to the United States District Court for the Eastern District of Arkansas. On December 2, 1953, the claimant filed a motion to set aside the remanding order of November 23, 1953. Such motion was overruled by Judge Miller on December 11, 1953. Pursuant to Judge Miller's order, the case was remanded to the Eastern District of Arkansas. In remanding the case, Judge Miller, whose opinion appears in 117 F. Supp. 110, held that his court was without jurisdiction.

"On December 21, 1953, the claimant filed a motion in the Eastern District of Arkansas, asking that the case be dismissed or re-transferred to the Western District of Arkansas pursuant to the stipulation referred to herein. Chief Judge Trimble of that court, in an opinion and order dated June 14, 1955, held that his court was without jurisdiction to proceed in the case and that,

> * * * due to the refusal of the court of the Hot Springs Division of the Western District of Arkansas to accept said transfer, it would not be proper for this court to make a re-transfer of the case, but that an order dismissing the cause should be deferred for a period of sixty days in order to enable libelant, if it so desires, to apply to the Court of Appeals for a writ of mandamus to determine the proper forum for the trial thereof.

"We have thus presented a question of jurisdiction as between two District Courts within this Circuit, each holding that it is without power or jurisdiction to proceed with the trial of the case. A stalemate or impasse is created which, in the opinion of this court, justifies the exercise of its power to determine the question of jurisdiction. The order of Chief Judge Trimble is not an appealable order. However, no good could come of, and considerable delay and possibly harm could be caused by, awaiting an order of dismissal from the District Court for the Eastern District of Arkansas, Western Division, and appeal therefrom. Chief Judge Trimble has held that his court does not have jurisdiction. If he is right, then he does not have jurisdiction to dismiss and there would be nothing from which to appeal. It would be improper for this court to allow such a stalemate to continue. The matter should be dealt with now so that the case may be properly tried in the court having jurisdiction thereof. *Ex Parte Simons, Petitioner*, 247 U.S. 231 (1917); *Barber Asphalt Pav. Co.* v. *Morris, Judge*, 132 F. 945 (8th C.C.A.); *C-O-Two Equipment Co.* v. *Barnes, Judge*, 194 F. 2d 410 (7th C.C.A.); *Wiren* v. *Laws*, 194 F. 2d 873 (D.C.C.A.).

"The question presented is difficult. Two able and conscientious District Judges, after exhaustive review and the writing of carefully considered opinions, have arrived at diametrically opposed conclusions, each holding that his court is without jurisdiction. While this situation exists, the case itself hangs in mid-air with nothing being done to bring it to trial and proper conclusion.

"The solution of the problem lies in the interpretation given to 21 U.S.C. 334(a). That section, insofar as it may be pertinent to the problem, provides as follows:

> In any case where the number of libel for condemnation proceedings is limited as above provided *the proceeding pending or instituted shall*, on application of the claimant, seasonably made, *be removed for trial to any district agreed upon by stipulation between the parties*, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial. (Emphasis supplied.)

"In remanding the case to the Eastern District of Arkansas, Judge Miller said, in *U.S.* v. *353 Cases, More or Less, Mountain Valley Mineral Water*, 117 F. Supp. 110, 115:

> A reference to the statute discloses that the application of a claimant for transfer, whether upon stipulation or motion, must be made 'to the court of the district in which the seizure has been made, * * *.' The statute authorizes only one application and that must be to the designated court. If agreeable to all parties in a case of alleged misbranding, as in the instant case, the case may be transferred to 'any district agreed upon by stipulation between the parties,' but if the parties do not so stipulate then the designated court must, if a transfer is allowed, 'specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.' The claimant

exercised its right to a transfer from the court of original jurisdiction to a court permitted by the statute. In so doing it exhausted the statutory right to transfer and the case cannot be transferred again either on motion or stipulation.

* * * * * * *

"If the parties are allowed, by stipulation, to transfer a case a second time, there is no reason why they could not transfer it as many times as they might desire and thus control the jurisdiction of the federal courts by various stipulations.

"We are unable to agree with Judge Miller in his conclusions. In dealing with the application for transfer based on stipulation, the statute refers to a case 'pending or instituted,' from which it is fair to assume Congress meant some court in addition to that wherein the case was 'instituted'; in other words, to a court where it might be 'pending' as distinguished from where it was 'instituted.' Such an interpretation presupposes the possibility of at least one transfer to get from the court where the case was 'instituted' to where it was 'pending.'

"The statute does not limit the number of applications to one. It is, in fact, silent on that question and it is only by inference, as above, that the thought of more than one application is arrived at. Granted that the matter is not free from doubt, we prefer the more liberal view and do not believe the parties were bound by or limited to one application and only one where a stipulation has been entered into between them.

"In passing the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301, et seq.), Congress recognized that extreme hardship might result to claimants whose property had been seized in distant jurisdictions. A manufacturer with its principal place of business in California might have property seized in Maine. The difficulties of property defending the libel action in the district where the property was seized, such as in the production of documents or other exhibits, the availability of witnesses and the readiness of other information, together with the expense, might make it impossible for a claimant to obtain justice. Congress accordingly provided, in 21 U.S.C. 334(a), that the proceeding 'pending or instituted' could be removed for trial 'to any district agreed upon by stipulation between the parties.' In the event of failure to so stipulate, Congress provided that the claimant 'may apply to the court of the district in which the seizure has been made, and such court shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business.'

"In the instant case, the parties apparently were at first unable to agree upon a place for trial and accordingly it became necessary for the claimant to make application to the court of original jurisdiction for transfer. That transfer or removal could not be to the district of the claimant's principal place of business but only to 'a district of reasonable proximity' thereto. It will be noted that the statute involved, in referring to claimant's petition for removal, specifically provides that such application shall be 'to the court of the district in which the seizure has been made.' As already pointed out, no such restriction is found where the parties have agreed by stipulation upon the place of trial. Such application, based on stipulation, may be made to any court where the case is pending. Nowhere in the statute will be found any provision to the effect that a claimant has exhausted its statutory right to transfer by stipulation through having made application to the court of original jurisdiction for removal and we cannot accept such constrained view of the statute.

"In the case of *United States* v. *45⅔ Dozen Packages, More or Less, of U-X Improved Shaving Medium*, 46 F. Supp. 112, the court, under identical facts such as we are concerned with here, said, at page 112:

> Claimant contends that the order transferring the case to this court had been consented to by the United States Attorney for the District of Connecticut, and, accordingly, such transfer was permissible under the statute. I agree with this contention. The statute specifically provides that a proceeding 'pending or instituted' shall on application of the claimant be removed to any district agreed upon by stipulation between the parties. The consent of the United States Attorney for the District of Connecticut was in effect a stipulation. Nowhere is it provided that by

stipulation a proceeding may be transferred only once, and then only to a district where the claimant does not have his principal place of business.

"In *United States* v. *Six Dozen Bottles, More or Less, of 'Dr. Peter's Kuriko,'* 55 F. Supp. 458, D.C.E.D. Wisc. 1944, the court denied a second request by claimant for a compulsory removal. In the opinion, Judge Duffy, now Judge of the United States Court of Appeals, 7th Circuit, said:

> The power of removal is exclusively conferred under the act upon the court of original jurisdiction, *barring of course the existence of a stipulation of the parties on the subject. As the latter element does not obtain in the instant situation, this court has no power to grant the requested removal.* In other words, the right to removal is completely exhausted and no longer exists in this proceeding. (Emphasis supplied.)

"There would seem to be there inferred that if a stipulation had existed in that instance the court would have had the right to enter an order removing the case to the district provided for in such stipulation. To hold that the parties could not stipulate for a place of trial agreeable to both because the claimant had once made application to the court of original jurisdiction for removal would seem to us unduly restricting the parties and to defeat the intent of Congress to the effect that the case could be tried in any district agreeable to the parties as expressed by stipulation. We do not believe that Congress intended any limitation which it did not express.

"Argument has been made to the effect that this view or interpretation of the statute might result in continuous tranfer from one district to another, possibly through unwillingness on the part of United States Attorneys to try the case and to shift the burden elsewhere. We find no force to that argument. The United States Attorneys in the various districts are under the control of the Attorney General. The remedy for any such difficulty, should it arise, rests in his hands and can be easily exercised. We think the Congress intended that the parties should be allowed to stipulate trial in 'any district agreed upon' and that such right is a salutary one and that its exercise in many instances may operate in the interests of justice.

"In the instant case, it may well be that due to unfamiliarity with the problems involved the parties at first could not agree upon a place of trial. Subsequent to the original removal to the Eastern District of Arkansas, Western Division, the parties did agree that the case could best be tried in the home district of the claimant. This is consistent with the general idea that a party has a right to be tried in his home district unless such place of trial would otherwise appear improper.

"We hold that under the statute the parties had the right to stipulate a removal of the case from the Eastern District of Arkansas to the home district of the claimant and that the Western District of Arkansas, Hot Springs Division, has jurisdiction of the case. Accordingly, the writ of mandamus will be denied and it is ordered that the files in the case of *United States of America, Libelant,* v. *353 cases,* more or less, each containing 6 one-half gallon bottles, and 81 five-gallon carboys, more or less, of an article of food and drug labeled in part: 'Mountain Valley Mineral Water,' et al., Mountain Valley Sales Company, a corporation, Claimant, Civil No. 2682, be transferred from the Eastern District of Arkansas, Western Division, to the Western District of Arkansas, Hot Springs Division, in order that that court may be in a position to proceed with the case."

On 6–6–55, H. B. McFarling, the distributor of the seized water and pamphlets, Memphis, Tenn., filed a claim for the following described pamphlets: "The importance of Mountain Valley Water in Arthritis and Rheumatic Disorders," "The Importance of Mountain Valley Water in Kidney and Bladder Disorders," "The Story of Mountain Valley Mineral Water From Hot Springs, Arkansas," "Is Your Trouble Mineral Deficiency?," "Facts About Mountain Valley Mineral Water From Hot Springs, Arkansas," "Why Everyone Should Drink Two Quarts of Water Each Day," "How Much Mountain Valley Mineral Water Should I Drink."

On 6–6–55, John G. Scott, Yonkers, N.Y., appeared as claimant for the pamphlet, entitled "Helping To Stay Young Through Minerals."

The Government and the claimants each filed written interrogatories, which were subsequently answered in part, and in addition extensive depositions were taken.

The case came on to trial before a jury on 5–21–56, in the W. Dist. Ark., and was concluded on 6–2–56, when the jury rendered a verdict in favor of the claimants. On 6–2–56, the court in accordance with the jury verdict, entered a judgment in favor of the claimants and ordered the action dismissed.

At the close of the claimants' testimony, the Government filed a written motion for a directed verdict which was denied. After the jury verdict, the Government filed a motion for a judgment notwithstanding the verdict. This motion was denied on 8–1–56, (143 F. Supp. 219). The Government appealed and the judgment of the district court was reversed by the United States Court of Appeals for the Eighth Circuit on 8–6–57, in the following opinion (247 F. 2d 473):

SANBORN, *Circuit Judge:* "This is an appeal by the United States from an adverse judgment in a libel proceeding brought by it on August 19, 1953, in the Western District of Tennessee, for the condemnation, under § 304(a) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended; 21 U.S.C. § 334(a), of a quantity of allegedly misbranded Mountain Valley Mineral Water, bottled by the Mountain Valley Spring Company, of Hot Springs, Arkansas, and shipped in interstate commerce. At the time of seizure in the libel proceeding, the water and its accompanying sales literature was located at 2089 Madison Avenue, Memphis, Tennessee, in the possession of an authorized distributor, Henry Branson McFarling, doing business as Mountain Valley Water Company.

"How the case came ultimately to be tried, in the spring of 1956, before the United States District Court for the Western District of Arkansas and a jury, at Hot Springs, Arkansas, can be gathered from *United States* v. *United States District Court for the Eastern District of Arkansas*, 8 Cir., 226 F. 2d 238.

"The claim of the Government that the water was misbranded, and therefore subject to condemnation, was based upon the assertions; (1) that the 'labeling' (promotional sales literature and advertising), accompanying the water,[1] falsely represented it to be an adequate and effective treatment for various diseases and disorders, and contained other false statements [§ 502(a) of the Act; 21 U.S.C. § 352(a)];[2] and (2) that the water was represented for special dietary uses, and that its label did not bear the information concerning its mineral properties, determined by regulations (21 C.F.R. § 125.4, promulgated in 1941) to be necessary 'in order fully to inform purchasers as to its value for such uses,' as is required by § 403(j) of the Act; 21 U.S.C. § 343(j).[3]

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[1] By § 201(m) of the Act, 21 U.S.C. § 321(m), "labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article," in the sense of supplementing or explaining it. *Kordel* v. *United States* 335 U.S. 345, 350; *V. E. Irons, Inc.* v. *United States*, 1 Cir. 244 F. 2d 34, 39. "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article; * * *." Sec. 201(k) of the Act; 21 U.S.C. § 321(k).

[2] "§ 352. [21 U.S.C.] *Misbranded drugs* * * *

"A drug * * * shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular."

[3] "§ 343. [21 U.S.C.] *Misbranded food*

"A food shall be deemed to be misbranded—

* * * * * * *

"(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the [Federal Security] Administrator [the Secretary of Health, Education, and Welfare since April 11, 1953, 67 Stat. 631, 632] determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses."

"Food" is defined by § 201(f) of the Act, 21 U.S.C. § 321(f) as "(1) articles used for food or drink for man or other animals, * * *."

"The Mountain Valley Sales Company, of Hot Springs, Arkansas, a subsidiary of the Mountain Valley Spring Company which bottled the water, filed a claim for the water and a separate claim for '24 pamphlets, more or less, entitled "Your Health Begins With Nature",' and '24 pamphlets, more or less, entitled, "Mountain Valley Water From Hot Springs, Arkansas, in Pregnancy and Care of Children",' which pamphlets had been seized in the libel proceeding.

"John G. Scott, of Yonkers, New York, 'the Mountain Valley distributor in New York and in the New York area,' filed a claim asserting ownership of three of the seized pamphlets entitled, 'Helping to Stay Young Through Minerals.' He moved to dismiss the libel as to the three pamphlets on the ground that they did not constitute labeling and had been unlawfully seized. He also moved to suppress the pamphlets as evidence, on the ground that they had been obtained in violation of his constitutional rights; this upon the theory that Government Agents had unlawfully used decoys and subterfuge in procuring the pamphlets from the Memphis distributor.

"McFarling, the distributor from whom the water and pamphlets were taken, filed a claim for the following seized literature, of which he asserted he was the owner:

> 146 pamphlets, more or less, entitled 'The Importance of Mountain Valley Water in Arthritic and Rheumatic Disorders'
> 80 pamphlets, more or less, entitled 'The Importance of Mountain Valley Water in Kidney and Bladder Disorders'
> 7 pamphlets, more or less, entitled 'The Story of Mountain Valley Mineral Water from Hot Springs, Arkansas'
> 123 pamphlets, more or less, entitled 'Is Your Trouble Mineral Deficiency?'
> 500 pamphlets, more or less, entitled 'Facts About Mountain Valley Mineral Water from Hot Springs, Arkansas'
> 4 pamphlets, more or less, entitled 'Why Everyone Should Drink Two Quarts of Water Each Day'
> 50 pamphlets, more or less, entitled 'How Much Mountain Valley Mineral Water Should I Drink?'

McFarling also filed a motion to suppress the pamphlets as evidence.

"The trial court deferred ruling on the several motions to suppress evidence and to dismiss the libel, until the trial of the case on the merits. The motions ultimately disappeared from the case.

"All of the claimants were represented by the same counsel. It is apparent from the record that the party most interested in defending against the libel was the Mountain Valley Spring Company, of Hot Springs, Arkansas. It has for many years bottled the water from the Mountain Valley Spring, which is located about ten miles by road from the city of Hot Springs, and has sold the water rather generally throughout the United States to authorized distributors, and to dealers through its subsidiary the Mountain Valley Sales Company.

"At the trial, the issues were: (1) whether the sales literature introduced in evidence by the Government constituted 'labeling' of the water within the meaning of 21 U.S.C. § 321(m); (2) whether the labeling was 'false or misleading in any particular' [21 U.S.C. § 352(a)]; and (3) whether the water was represented for special dietary uses.

"The Government, having the burden of proof, first introduced its evidence tending to support its charges that the representations contained in much of the sales literature with respect to the medicinal and therapeutic qualities of the water were false or misleading, and to show that the water was represented for special dietary uses. The claimants then introduced evidence to show that the representations contained in four pamphlets, which they contended were the only ones used by the Memphis distributor, and therefore the only ones constituting 'labeling,' were not false or misleading. They denied that the water was represented for special dietary uses, but did not claim that the labels on the bottles contained the information required by 21 U.S.C. § 343(j).

At the close of the claimants' evidence, the Government made a written motion for a directed verdict on the grounds:

> The uncontroverted evidence in this case shows that Mountain Valley Mineral Water is recommended and suggested for use as a food for special dietary uses because of its mineral content. The labels on both sizes of bottles seized fail to bear the information required by 21 U.S.C. [§] 343(j) and 21 C.F.R. [§]125.4. For this reason, the mineral water is, as a matter of law, misbranded within the meaning of 21 U.S.C. [§] 343(j) and should be condemned pursuant to 21 U.S.C. [§] 334 (a) & (b).

In ruling upon the motion, the court said:

> Now, this motion of the plaintiff or libelant for a directed verdict on the question of the alleged misbranding of the water as appearing in the exhibit, the bottles introduced here, raises this question. Water may be considered a food when used under the statute for dietary uses. Now, if the court was satisfied that this water was recommended for special dietary uses, then I think the motion probably should be granted, but I am not certain at all on that. * * * I think that is a question that the court must submit to the jury.

At the time of this ruling, the trial was virtually at an end so far as the taking of evidence was concerned, and the court was considering requests for instructions. The court then said to counsel: 'I think we can reasonably assume that the testimony will close this afternoon, at 2:30 or 3:00.' The record shows that the Government called two rebuttal witnesses, and the claimants called one witness on surrebuttal. This additional testimony had nothing to do with the question whether the water was represented for special dietary uses. At the close of this rebuttal evidence, the Government's motion for a directed verdict was not renewed. But when the court called upon counsel for their objections, if any, to the instructions, counsel for the Government said:

> The libelant has no objections except for the failure to direct a verdict upon the charge that the water is misbranded because it fails to bear statements required by Section 343–J, of the Federal Food, Drug, and Cosmetic Act, since it is represented as a food for special dietary uses because of its mineral content * * *.

The court overruled the objection.

"The jury's verdict found all issues in favor of the claimants. The Government moved for judgment notwithstanding the verdict, in accordance with its motion for a directed verdict. This the court denied on the grounds (1) that by not renewing the motion for a directed verdict at the close of the entire evidence, the motion was waived, and (2) that the issues were all issues of fact and the verdict of the jury was supported by the evidence. The opinion of the court is found at 143 F. Supp. 219.

"The claimants now insist that the failure of the Government to renew its motion for a directed verdict after the last witness had testified precludes the review of the question whether, under the evidence and the applicable law, the case was mistakenly submitted to the jury.

"*O'Malley* v. *Cover*, 8 Cir., 221 F. 2d 156, states the well known general rule that to preserve for review the question of the sufficiency of the evidence to take a case to the jury, there must be a motion for a directed verdict at the close of the evidence. The Government contends that, under the evidence, misbranding of the water was conclusively proven, and that this was sharply, definitely and adequately called to the attention of the trial court by the motion for a directed verdict made at the close of all of the evidence which had anything to do with the grounds upon which the motion was based, as well as by the Government's objection, before the jury retired, to the court's failure to direct a verdict.

"We think that as a practical matter the Government did all that was necessary to preserve for review the question whether it was entitled to a directed verdict. This Court, moreover, in the public interest and to guard against injustice, may, of its own motion, notice errors which have not been properly preserved for review, if such errors are obvious, or if they otherwise seriously affect the fairness and integrity of the judicial proceedings. *United States* v. *Socony-Vacuum Oil Co., Inc.*, 310 U.S. 150, 239; *United States* v. *Bernays*, 8 Cir., 158 F. 791, 794; *New York Life Ins. Co.* v. *Rankin*, 8 Cir.,

162 F. 103, 108; *Baltimore & Ohio Railroad Co.* v. *McCune*, 3 Cir., 174 F. 991, 992; *Hart* v. *Adair*, 9 Cir., 244 F. 897, 900; *Ayers* v. *United States*, 8 Cir., 58 F. 2d 607, 609; *Prudential Ins. Co. of America* v. *Morris*, 3 Cir., 72 F. 2d 824; *Cox* v. *United States*, 8 Cir., 96 F. 2d 41, 43.

"We have not insisted upon technical perfection in the preservation of alleged errors for review. In the recent case of *Railway Express Agency, Inc.* v. *Epperson*, 8 Cir., 240 F. 2d 189, counsel for the defendant moved for a directed verdict at the close of the evidence, but his motion was defective in failing to state 'the specific grounds therefor,' as required by Rule 50(a) of the Federal Rules of Civil Procedure, 28 U.S.C.A. A ruling that the motion was inadequate to preserve for review the question of the sufficiency of the evidence to take the case to the jury would have been technically correct. We said (page 193 of 240 F. 2d): 'There was nothing specific about the grounds stated by defendant's counsel in his motion for a directed verdict. It is apparent, however, that the trial judge knew what counsel was driving at. So once again we shall accept intent for performance.' And Rule 1 of the Federal Rules of Civil Procedure provides that the rules 'shall be construed to secure the just, speedy, and inexpensive determination of every action.'

"The public has too vital an interest in the proper and truthful labeling of whatever is sold for human consumption to justify basing a decision upon what, under the circumstances, was a mere technical oversight which misled neither the trial court nor opposing counsel. If, under the evidence and the applicable law, the water was misbranded, it ought to be condemned in the public interest. 'The problem is a practical one of consumer protection, not dialectics.' *United States* v. *Urbuteit*, 335 U.S. 355, 358.

"How much of the sales literature seized with the water in Memphis constituted 'labeling' within the meaning of 21 U.S.C. § 321(m) was an issue in the case. Of the eight pamphlets seized in the distributor's place of business and introduced in evidence, the claimants conceded that four were 'labeling,' namely those entitled: 'Facts About Mountain Valley Mineral Water from Hot Springs, Arkansas'; 'How Much Mountain Valley Mineral Water Should You Drink?'; 'The Importance of Mountain Valley Water in Arthritic and Rheumatic Disorders'; and 'The Importance of Mountain Valley Water in Kidney and Bladder Disorders.' The other four, which bore the following titles, 'Mountain Valley Water from Hot Springs, Arkansas, in Pregnancy and Care of Children'; 'Your Health Begins With Nature'; 'Is Your Trouble Mineral Deficiency?'; and 'The Story of Mountain Valley Mineral Water from Hot Springs, Arkansas,' the Government contended were also 'labeling.' The claimants, however, insisted that they were not. This, ostensibly, because of evidence that they had not been used by the distributor in connection with selling the water in Memphis. However, all of the pamphlets were obviously printed for use generally in promoting the sale of the water, and were useful for no other purpose. All of them were found in the place of business of the local distributor, and were approved advertising matter, available upon request. The President of the Mountain Valley Spring Company testified, as a witness for the claimants, that he knew of no sales literature being printed that was not approved.

"The interpretation accorded the phrase 'special dietary uses' by the agency selected by Congress to enforce the Federal Food, Drug, and Cosmetic Act is found at 21 C.F.R. § 1.11, and reads as follows:

> § 1.11 *Special dietary uses.* (a) The term 'special dietary uses,' as applied to food for man, means particular (as distinguished from general) uses of food, as follows:
>
> (1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
>
> (2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;
>
> (3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular

use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

* * * * * * *

"We do not propose to set out in this opinion all of the statements in all of the pamphlets, which the Government contends were conclusively shown by the evidence to constitute 'labeling,' representing that the water has 'special dietary uses.' From the sales literature received in evidence, it is clear that the water was recommended for such uses. In the pamphlet 'Facts About Mountain Valley Mineral Water from Hot Springs, Ark.' (conceded by claimants to be 'labeling'), the following appears:

What makes it so helpful?

* * * * * * *

4. Its low sodium. Mountain Valley Water, with less than 3 parts per million, is ideal for the low-salt diet often advised in High Blood Pressure and Congestive Heart conditions.

5. Its aid to digestion. When used daily for a few weeks, Mountain Valley Water tends to improve the digestion of protein and fat substances of food.

* * * * * * *

7. Its helpful trace minerals, including fluorine for teeth and dental caries.

* * * * * * *

Does it Over-mineralize the System? No. Laboratory research indicates that the predominant mineral in Mountain Valley Water—calcium—is utilized by the body, but where the body already receives an adequate supply of calcium, the drinking of Mountain Valley Water does not tend to increase the amount of calcium in the body.

* * * * * * *

Where Mountain Valley Water is not being used as an aid in treatment, it is usually consumed in place of ordinary water, with and between meals.

"In 'How Much Mountain Valley Mineral Water Should I Drink?,' appears:

With Meals—Competent medical opinion today advises water with meals. Mountain Valley is especially suitable, furnishing assimilable calcium, magnesium and other vital minerals.

"In 'The Importance of Mountain Valley Water in Kidney and Bladder Disorders,' appears the statement that 'Pure Mountain Valley Water contains certain minerals which help proper kidney function.'

"In 'Your Health Begins with Nature,' which the claimants deny was 'labeling,' but which, we think, obviously was 'labeling,' there were many statements representing the water as a dietary supplement. The following are examples:

The influence of Mountain Valley on the metabolic process, the changing of food to heat-energy, is most healthful. This assistance benefits all ages—from infants to elderly men and women. Children need Mountain Valley Water to supplement the calcium they use for teeth and bones. Adults appreciate Mountain Valley for the general 'good health' which seems to be with those who drink it regularly.

* * * * * * *

Mineral Analysis in Parts Per Million

Calcium Bicarbonate—315.43—The rich calcium intake available in Mountain Valley Water helps prevent decalcification in many cases. It contributes to the bone-building process, helps ward off bone diseases, and stimulates kidney secretion.

* * * * * * *

Sodium—2.88—Mountain Valley's remarkably low sodium content is especially important to persons suffering from congestive heart failure

high blood pressure, and certain kidney conditions. It is often recommended by doctors to patients on low sodium diets.

* * * * * * *

Pregnancy

* * * * * * *

Mountain Valley is also prescribed for its high assimilable calcium content. During the latter half of pregnancy, the mother is required to supply the baby large amounts of calcium for bone building. If sufficient calcium isn't supplied by the mother's diet, decalcification of the mother's bones or teeth often occurs.

Frequently during pregnancy the attending physician will recommend a low salt diet. In such cases Mountain Valley is particularly advisable because of its exceptionally low sodium content.

Diarrhea.

During infancy and sometimes adulthood, chronic diarrhea may be complicated by the development of tetany, a condition of muscular spasms which is due to inadequate calcium in the blood. A similar condition occurs in certain disturbances of the parathyroid glands. Under both of these circumstances, Mountain Valley Water, because of its usable calcium, is a valuable dietary adjunct.

"The other pamphlets in evidence we think are largely cumulative and need not be referred to.

"We think that all of the sales literature received in evidence was, as a matter of law, 'labeling' (see and compare, *Kordel* v. *United States*, 335 U.S. 345, 350; *United States* v. *Urbuteit*, supra, 335 U.S. 355, 358; *V. E. Irons, Inc.* v. *United States*, 1 Cir., 244 F. 2d 34, 39), and that the question whether the literature was 'labeling' was not an issue for the jury.

"While no question as to the validity of regulation § 1.11 (21 C.F.R.) defining 'special dietary uses' was raised in the trial, and although a federal appellate court is seldom justified in ruling upon a question not raised or ruled upon at the trial (*Warner* v. *Dworsky*, 8 Cir., 194 F. 2d 277, 278), the claimants challenge the validity of the regulation upon the ground that it was not issued pursuant to a hearing, evidence, and detailed findings of fact, as required by § 701(e) of the Act; 21 U.S.C. § 371(e). We cannot agree. The regulation is an interpretative ruling which merely states the meaning accorded to the phrase 'special dietary uses' by the Federal Food and Drug Administration. The ruling was adopted more than fifteen years ago. It did not prescribe the information which must appear on the label of the containers for foods for special dietary uses. The regulations prescribing the required information appear at 21 C.F.R. § 125.4 It is unnecessary to set them out in this opinion, since it is conceded that the labels on the bottles did not contain the required information. These regulations were adopted after notice and hearing, and the contention that they are invalid because the ruling § 1.11 explaining the meaning the Food and Drug Administration proposed to place on the phrase 'special dietary uses' was issued without notice and hearing, we regard as without merit.

"In *Gibson Wine Co., Inc.* v. *Snyder*, D.C. Cir., 194 F. 2d 329, 331, the court said:

> The distinctive chacteristics of interpretative rulings, as contrasted with so-called regulations, have long been recognized. Administrative officials frequently announce their views as to the meaning of statutes or regulations. Generally speaking, it seems to be established that 'regulations,' 'substantive rules' or 'legislative rules' are those which create law, usually implementary to an existing law; whereas interpretative rules are statements as to what the administrative officer thinks the statute or regulation means. * * *.

"In fairness to the claimants, it should be said that no suggestion has been made that the water in suit is adulterated or is not a wholesome, natural mineral spring water, suitable for human consumption. The Federal Food and Drug Administration, which the claimants evidently regard as unjustifiably intermeddling in their affairs, does not see eye to eye with them in regard to many of their representations of the curative, remedial, medicinal

and dietary properties of the water. Some of these representations are unquestionably fanciful, and some, no doubt extravagant. It seems unfortunate that the water should not be sold for what it is and in conformity with the applicable regulations of the Federal Food and Drug Administration.

"Our conclusion is that the water in suit was conclusively shown to be misbranded, because it was represented, by its labeling, for special dietary uses and because the labels on the bottles did not contain the information required by the applicable regulations.

"The judgment appealed from is reversed, and the case is remanded with directions to enter a judgment of condemnation."

Following the opinion of the court of appeals, the district court entered the following judgment on 12–19–57:

MILLER, *District Judge:* "The mandate of the United States Court of Appeals for the Eighth Circuit on the appeal of the libelant heretofore taken in this cause having been transmitted to the Clerk of this Court and filed herein on August 29, 1957, and the same having been brought to the attention of the Court, and upon consideration of the mandate and of the opinion of the United States Court of Appeals for the Eighth Circuit referred to in the mandate, in compliance therewith it is hereby

"ORDERED, ADJUDGED AND DECREED by this Court as follows:

"1. That the judgment of this Court entered herein on June 2, 1956, be and the same is hereby vacated and set aside and the libel of information reinstated;

"2. That pursuant to the verdict herein returned on June 6, 1956, with respect to the charges contained in Paragraphs 3 and 5 of said libel of information, alleging a misbranding of said water within the meaning of 21 USC 352(a) and 21 USC 343(a) because of false and misleading representations, which issues were submitted to the jury by consent of the parties, and in accordance with said jury verdict in favor of the claimants on all said issues, the charges contained in Paragraphs 3 and 5 of said libel of information are hereby dismissed with prejudice to the libelant;

"3. That as a matter of law the water in suit was misbranded within the meaning of 21 USC 343(j) because it was represented by its labeling as a food for special dietary uses by reason of its mineral content and because the labels on the bottles did not contain the information required by that section and by the applicable regulations appearing at 21 CFR 125.4; that by reason of said violation of 21 USC 343(j) said water under seizure is hereby condemned and forfeited to the use of the United States;

"4. That the United States Marshal for this District destroy the water libeled herein pursuant to this judgment of condemnation;

"5. That the libelant have and recover from the claimant, Mountain Valley Sales Company, the court costs and fees of this action, including storage and other proper expenses, which are directly referable to the misbranding adjudged herein."

After the judgment was entered on 12–19–57, the Government filed a Petition for a Writ of Mandamus asserting that the judgment was not in accord with the opinion of the court of appeals (247 F. 2d 473).

On 5–28–58, the court of appeals handed down the following opinion (256 F. 2d 89):

PER CURIAM.

"This Court, on August 6, 1957, in *United States* v. *353 Cases * * * Mountain Valley Mineral Water*, a libel proceeding, reversed the judgment appealed from. The judgment in favor of the claimants was based upon the verdict of a jury finding all issues in their favor. The reversal of the judgment by this Court was based upon its conclusion that all of the sales literature involved in advertising the water was, as a matter of law, 'labeling'; that the evidence conclusively showed that the mineral water in suit had been recommended for special dietary uses, and that the labels on the bottles did not contain the information required by applicable regulations; that, at the close of the evi-

dence, the Government was entitled to a directed verdict, and that the trial court erred in denying the Government's motion for such a verdict. We remanded the case with directions to enter a judgment of condemnation. 247 F. 2d 473.

"The parties, after the remand of the case, were unable to agree upon the form of judgment required by our opinion and mandate. Judge Miller, for the District Court, entered a judgment of condemnation, but, over the objections of the Government, included in it a paragraph 2 reading as follows:

> That pursuant to the verdict herein returned on June 6, 1956, with respect to the charges contained in Paragraphs 3 and 5 of said libel of information, alleging a misbranding of said water within the meaning of 21 U.S.C. § 352(a) and 21 U.S.C. § 343(a) because of false and misleading representations, which issues were submitted to the jury by consent of the parties, and in accordance with said jury verdict in favor of the claimants on all said issues, the charges contained in Paragraphs 3 and 5 of said libel of information are hereby dismissed with prejudice to the libelant.

This was done upon the theory that the claimants were, notwithstanding the reversal of the judgment appealed from in the libel proceeding, entitled to the benefit of so much of that judgment as was based upon the verdict of the jury with respect to the issue of alleged misrepresentations in labeling, insofar as that issue was claimed to be unrelated to the question of the alleged representations of the water for dietary uses. In providing for the recovery by the Government of costs and expenses in paragraph 5 of the judgment entered on our mandate, Judge Miller also added the words, 'which are directly referable to the misbranding adjudged herein.' To this the Government also objected.

"The purpose of the instant mandamus proceeding brought by the Government against Judge Miller is to secure the elimination from the final judgment of those portions above referred to.

"It is our opinion that every element and issue which inhered in the verdict upon which the judgment appealed from in the libel proceeding was based, disappeared from the case when this Court reversed that judgment and directed the entry of a judgment in favor of the Government on the ground that, under the evidence and as a matter of law, it was entitled to a judgment of condemnation at the close of the evidence. We are satisfied that the Government is entitled to have eliminated the challenged portions of the judgment which was entered after the remand of the libel proceeding.

"We think it is unnecessary to issue a writ of mandamus, since we have no doubt that Judge Miller will readily comply with this Court's views as to the form of judgment required by its mandate. He is directed to amend the judgment by eliminating paragraph 2 and striking out in paragraph 5 the words, 'which are directly referable to the misbranding adjudged herein.' As so amended the judgment will conform to the mandate of this Court."

A rehearing was denied by the court of appeals on 6–27–58. The claimants then applied to the United States Supreme Court for a writ of certiorari which was denied on 10–13–58 (358 U.S. 834). Subsequently, on 10–24–58, the judgment of the district court of December 19, 1957, was amended to comply with the order of the court of appeals of May 28, 1958, and the application for writ of mandamus was dismissed. The amended judgment contained simply a finding that the water under seizure was misbranded under Section 403(j), and provided for destruction of the water, with assessment against claimant of costs without qualification.

Thereafter, the claimants, Mountain Valley Sales Co. and H. B. McFarling, filed claims and motions for return of the water, containers, and pamphlets. On 6–24–59, the court denied the motion of Mountain Valley Sales Co., and ordered the water destroyed. In addition, the court ordered, after the destruction of the water, the release of the bottles, carboys, containers and pamphlets to the claimants.

The order further provided that neither it, nor the return of the articles and pamphlets to the claimants thereunder would constitute or imply any adjudication upon the issues of the truth or falsity of the claims appearing in said pamphlets under Sections 502(a) and 403(a) as charged in the libel, as the question of such truth or falsity had not been adjudicated.

26598. Bio-Zyme tablets. (F.D.C. No. 43314. S. No. 32–856 P.)

QUANTITY: 1 drum of 8,300 tablets at East Orange, N.J.

SHIPPED: 6–4–59, from Inwood, Long Island, N.Y.

LABEL IN PART: (Btl. label attached to drum) "100 Gelvets BIO-ZYME Nutritional Supplement * * * Each Bio-Zyme Gelvet contains * * * Vitamin B–1 * * * 5 mg. *MDAR* 500% Niacinamide * * * 20 mg. * Vitamin B–12 activity 6 mcg. MDAR—Minimum daily adult requirement * need in human nutrition established but no MDAR established Sole Distributors—American Pharmaceutical Products Co. 3033 Newark, New Jersey."

LIBELED: 7–27–59, Dist. N.J.

CHARGE: 402(b)(1)—while held for sale, the valuable constituents, vitamin B_1, vitamin B_{12}, and niacinamide, had been in part omitted or abstracted from the article; and 403(a)—while held for sale, the label statement "Bio-Zyme is a scientifically formuated synergistic combination of enzymatic factors with amino acids, minerals, protein and carbohydrate digestive enzymes plus vitamins of the B Complex group * * *" was false and misleading since there is no scientific justification for formulating a synergistic combination of enzymatic factors, and the label statement "Niacinamide * * * need in human nutrition established but no MDAR established" was false and misleading since the minimum daily requirement for niacinamide has been established.

DISPOSITION: 8–27–59. Default—destruction.

26599. Protein dietary supplement. (F.D.C. No. 43545. S. Nos. 69–681/2 P.)

QUANTITY: 1 case containing 10 1,000-tablet btls., 33 cases, 12 300-tablet btls. each, 12 cases, 12 80-tablet btls. each, and 7 1,000-tablet btls., 23 300-tablet btls., and 60 80-tablet btls., at Minneapolis, Minn.

SHIPPED: Between 4–30–59 and 6–17–59, from Omaha, Nebr., by Vitamin Industries.

LABEL IN PART: (Btl.) "Verne Gagne's Fortified Protein Three P's Protein Power Pack Dietary Supplement Distributed by Vitamin Industries, 1511 Davenport St., Omaha, Nebr. * * * Ingredients: The readily available natural food protein factors in Three P's are composed of a special, skillfully blended formulation consisting of Soya Lecithin, Soy Powder, Solids of defated, dehydrated milk, barley malt, Sucrose, Dextrose, Debittered Special Strain Yeast, with natural purified Bone Meal."

LIBELED: 9–23–59, Dist. Minn.

CHARGE: 403(a)—when shipped, the label statements, "Fortified Protein," "Protein Power Pack," "Champion of the World," and "Protein Concentrate," together with a picture of an athlete on the label, represented and suggested that the article was a fortified protein, that it was a protein concentrate, that its protein content would supply a significant amount of strength and power, and that the user would develop an athletic physique, which statements and design were false and misleading since they were contrary to fact; 403(e)(2)—a portion of the 80-tablet size bottle failed